

Patent Appl. No. 09/836,653  
Request for Continued Examination  
Amended Claims per Phone Interview 04/08/2004

Also, in accordance with provisions of SS1.136, we submit a Pethion for Extension of Time. Final Office Action dated 01/09/2004, with shortened response period of 3 months, requires extension of 3 months to extend through this filing of 07/09/2004.

Finally, the Credit Card Payment form is included to cover fees associated with above forms. These include the small entity fee of \$385 for Request for Continued Examination, plus Extension fees of \$475 for three months as per 1.17a3.

Amendments to the Claims begin on page 3 of this paper.

Please accept these claims as discussed. Also enclosed is Request for Interview — please call us when you are beginning examination and we can review to date.

Respectfully,

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#### AMENDMENTS TO THE CLAIMS

Please cancel Claims 2, 3, 9, 10 and amend Claims 1, 4-8, and 11-14 as follows:

1. (Currently amended) A method for creating a customized clinical trial database management system for use in conducting a clinical trial, the method comprising:

providing a user with at least one question related to an anticipated use of the customized database management system, wherein the anticipated use comprises administration of a clinical trial;

receiving at least one answer to the at least one question from the user;

retrieving a set of clinical trial governance rules that govern the management of data acquired during a clinical trial, ~~associated with the anticipated use of the customized database management system~~;

analyzing the at least one answer and the set of clinical trial governance rules; and

generating the customized clinical trial database management system according to the analyzing of the at least one answer and the set of clinical trial governance rules, whereby the generated clinical trial database management system is configured to govern the conduct of a clinical trial and to manage data acquired during the clinical trial.

2. (Canceled)

3. (Canceled)

4. (Currently amended) The method for creating a clinical trial database management system of claim 31 wherein the set of clinical trial governance rules is derived from clinical trials regulations.

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5. (Currently amended) The method for creating a clinical trials database management system of claim 1 wherein the set of clinical trial governance rules governs the at least one answer.

6. (Currently amended) The method for creating a clinical trials database management system of claim 5 wherein the generating creates a customized database management system that is in conformance with the set of clinical trial governance rules and the at least one answer.

7. (Currently amended) The method for creating a clinical trials database management system of claim 1 wherein the providing a user with at least one question, the receiving at least one answer, the retrieving a set of clinical trial governance rules, the analyzing, and the generating are all performed on a common Web site.

8. (Currently amended) A creation system for generating a customized database management system used to conduct a clinical trial, the creation system comprising:

a computer configured to execute a first routine for asking a user at least one question related to a desired application for the customized clinical trial database management system and for receiving at least one answer to the at least one question from the user;

the computer further configured to execute a second routine for retrieving a set of clinical trial governance rules that govern the management of data during a clinical trial associated with the desired application for the customized database management system;

the computer further configured to execute a third routine for processing an analysis of the at least one answer and the set of clinical trial governance rules; and

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the computer further configured to execute a fourth routine for generating the customized clinical trial ~~relational~~ database management system according to the analysis.

9. (Canceled.)

10. (Canceled.)

11. (Currently amended) The creation system of claim ~~408~~ wherein the set of rules is in conformance with clinical trials regulations.

12. (Currently amended) The creation system of claim ~~408~~ wherein a generated customized clinical trial database management system is in conformance with the set of rules and the at least one answer.

13. (Currently amended) The creation system of claim ~~408~~ wherein the asking and receiving are handled by a dialogue box described by software executed by the computer.

14. (Currently amended) The creation system of claim ~~408~~ wherein the first routine, second routine, third routine, and fourth routine reside at a common Web site.

15. (Original) A method for creating a clinical trials database management system, the method comprising:

providing information descriptive of a particular clinical trial;

providing a first set of rules in accordance with clinical trials governing regulations;

generating a second set of rules that conforms to the information and to the first set of rules; and

generating the clinical trials database management system to be compliant with the second set of rules.

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16. (Original) The method of claim 15 wherein the clinical trials database management system is contained within a Web site.

17. (Original) The method of claim 16 wherein the clinical trials database management system is operable on the Web site.

18. (Original) The method of claim 15 wherein the information descriptive of a particular clinical trial includes a user name, and data collection specifications.